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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,011	09/05/2003	Ann M. Maloney	10/041-2-C2	1738

28510 7590 02/08/2006

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,011	MALONEY, ANN M.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment, remarks and request for extension of time, all filed 11/17/05. Claims 50-54 are pending.

Claim Rejections - 35 USC § 103

1. Claims 50-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable over McClelland et al. (US 5,350,584) in view of Chow et al. (US 4,859,461) and further in view of Bodmeier et al. ("Effect of ion exchange resins on the drug release from matrix tablets," in European Journal of Pharmaceutics and Biopharmaceutics, 46, (1998), pp 321-327; provided by applicants).

Applicant argues:

a) The present invention does not require manufacturing steps of wet granulation, spheronization and drying, which are steps required by McClelland,

b) The present invention does not require or include coating of the ion exchange resin prior to incorporation into the dosage form and does not describe adsorption of drug onto the ion exchange resin to form drug-resin particles.

c) The process of McClelland and Chow are vastly different, and one of ordinary skill in the art would not prepare the dosage form by following the teachings of McClelland and Chow.

d) The teachings of McClelland and Chow would direct the person of ordinary skill in the art to pre-treat the ingredients prior to the manufacturing process and this applicant argues would slow the release of medicament.

e) Eichman describes production of drug-resin complex and the stabilization of the complex by addition of a chelating agent; Eichman further describes the coating of the drug-resin complex.

2. Applicant's arguments filed 11/17/05 have been fully considered but they are not persuasive.

Applicant's arguments a) – d) are generally directed to preparation and manufacturing processes. Therefore, for arguments a) through d), it is noted that the claimed invention is a product and how the product is made does not provide patentable distinction to the product. It is further noted that the claim recites the process of mixing cationic exchange resin and the oxycodone in dry form and then compressing the mixture. However, although, the claims recite a process of mixing the ion exchange resin and the oxycodone or the salt of the oxycodone followed by compression, determination of patentability is based on the product itself, and product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "... The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Once a product appearing to be substantially identical is found and a 35 U.S.C. 103 rejection made, the burden shifts to the applicant to show an unobvious difference, and "the Patent Office

bears a lesser burden of proof in making out a case of prima facie obviousness for product-by-process claims because of their peculiar nature" than when a product is claimed in the conventional fashion. *In re Fessmann*, 489 F.2d 742, 744, 180 USPQ 324, 326 (CCPA 1974). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. In re Marosi, 710 F.2d 798, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

Regarding e) Eichman was only relied upon for teaching that IRP-69 and IRP-70 are equivalent. Eichman was not relied upon for processes of manufacture of the dosage form and the patentability of the product is not determined on its method of production, but patentability is determined based on the product itself as discussed above.

The Rejection

McClelland discloses a formulation that contains a copolymer of acrylic acid and divinylbenzene (AMBERLITE-IRP 64) or styrene-divinylbenzene (AMBERLITE-IRP 69) and oxycodone or hydrocodone as examples of the drugs (column 2, line 62 to column 3 line 2; column 5, lines 13 and 14). The formulation of McClelland further contains excipient selected from polyvinylpyrrolidone, methylcellulose and polyethylene glycol (column 5, lines 45-48). McClelland discloses polyvinylpyrrolidone or methylcellulose as the excipient instead of hydroxypropylmethyl cellulose or hydroxypropyl cellulose or hydroxyethyl cellulose.

Chow discloses a composition that comprises AMBERLITE-70 and pharmaceutically active basic drugs selected form dextromethorphan, codeine, hydrocodone, morphine and

propranolol and an impregnating agent selected from hydroxypropylmethyl cellulose, hydroxypropyl cellulose, sorbitol, hydroxypropyl sorbitol, and polyvinylpyrrolidone for a prolonged continuous release of the active drugs. Chow further discloses that the hydroxyl alkyl celluloses are present in amounts ranging from about 3% to about 20% and that the polyvinylpyrrolidone are present in amounts ranging form 7% to 20%. See column 1, lines 36-58 and column 2, lines 12-63. The particle size of the resin is from about 25 μm to about 1,000 μm (column 2, lines 53-57).

Chow is relied upon for disclosing a combination of hydrocodone and hydroxypropylmethylcellulose or polyvinylpyrrolidone. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the oxycodone composition of McClelland and use hydroxypropylmethylcellulose as the carrier. Bodmeier discloses that incorporation of ion exchange resin into hydroxypropylmethylcellulose modifies the release of drugs; and amount and particle size of the resin particles of the carrier influences drug release. Therefore, one having ordinary skill in the art would have been motivated to use the hydroxypropylmethylcellulose and particles having the appropriate size to modify the drug release.

3. Claims 50 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McClelland et al. (US 5,350,584) in view of Chow et al. (US 4,859,461) and further in view of applicants admitted prior art.

McClelland and Chow are discussed above. The combined reference of McClelland and Chow does not include phenolic amine resin. Examples of phenolic amine resins are AMBERLITE IRP-58 (applicants' specification at paragraph [0027] of the published application

20040062812). Applicants are aware that IRP-58 and IRP-69 are equivalent and as a teaching reference IRP-69 and IRP-70 are equivalent (Eichman, US 5,980,882, column 6, lines 45-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare oxycodone-containing formulation and to substitute IRP-70 or IRP-69 with IRP-58 with the expectation of producing analgesic formulation.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BF

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